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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/008,957 01/20/98 MORIARTY

HM22/0910

BULLWINKEL PARTNERS  
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CHICAGO IL 60603-1493

EXAMINER

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ART UNIT	PAPER NUMBER
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11

RADIO B  
DATE MAILED:

1616

09/10/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/008,957

Applicant(s)

Moriarty et al.

Examiner

Sabiha Qazi

Group Art Unit

1616



☒ Responsive to communication(s) filed on Jul 8, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-19 is/are pending in the application.

Of the above, claim(s) 7-9 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-6 and 10-19 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 8

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **Final Office Action on the Merits**

### **Status of the Application**

1. Claims 1-19 are pending in the present application. Claims 7-9 stand withdrawn from further consideration as being drawn to a non-elected invention. Claims 1-6 and 10-19 stand rejected as indicated below.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112***

3. The rejection of claims 2-4 and 10-12 under 35 USC 112, second paragraph as being incomplete is withdrawn.
4. The rejection of claims 5-6 and 13-14 under 35 USC 112, second paragraph, as being incomplete for omitting essential elements, is maintained and claims 18 and 19 are rejected under 35 USC 112, second paragraph as being incomplete for omitting essential elements.

The structure of formula I is not identified in the instant claims as indicated in the previous Office Action.

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For this reason, the rejection of claims 5-6 and 13-14 under 35 USC 112, second paragraph, as being incomplete for omitting essential elements, is maintained and claims 18 and 19 are rejected under 35 USC 112, second paragraph as being incomplete for omitting essential elements.

### ***Claim Objections***

5. **The objection of claims 13-14 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn.**

6. The objection of claims 10-12 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is maintained and claims 2-4 and 15-17 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

The instant claims recite a "compound of formula I of claim 1". However, the variables (i.e.,  $R^1$ ,  $R^2$ ,  $R^3$  and  $R^4$ ) recited by the instant claims are not as defined by claim 1. Therefore, the definition of the compound of formula I as recited by claim 1 does not encompass the compounds recited by claims 2-4.

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It is suggested that the structure of formula I be included in each of the instant claims.

***Claim Rejections - 35 USC § 103***

7. The rejections of (1) claims 1-6 and 10-14 under 35 USC 103(a) over (1) Holick et al. ('538); (2) Holick et al. ('643); (3) Bishop et al. ('429) and claims 1-4 and 10-12 under 35 USC 103(a) over Gulbrandsen et al. ('790) are maintained and claims 15-19 are rejected under 35 USC 103(a) over (1) Holick et al. ('538); (2) Holick et al. ('643); (3) Bishop et al. ('429) and claims 15-17 are rejected under 35 USC 103(a) over Gulbrandsen et al. ('790).

Applicant argues (1) the properties of compounds taught by Holick et al. differ from those of the claimed compounds and that the reference does not teach a synthetic route of any vitamin D compound; (2) Bishop et al. do not provide any process for making the compound and does not provide any data for  $1\alpha$ -hydroxyvitamin D<sub>5</sub>; (3) the claimed compounds exhibit a very different therapeutic/toxicologic profile than vitamin D analogs taught by Gulbrandsen et al. The arguments are not persuasive for the following reasons.

Applicant's arguments against the lack of a synthetic process by Holick ('538 and '643) and Bishop for the preparation of the prior art compounds are noted. However, because the cited reference are US patents, one would assume that the

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disclosure is enabling and , thus, that the compounds taught by the prior art are enabled and the production of the compounds are readily known in the art (see Holick et al., '538, col. 11, line 57 - col. 12, line 9).

Applicant argues that the properties of the compounds taught by prior art differ from those of the claimed compounds. However, it is noted that the instant claims are drawn to compounds and not to a method of use of the instant compounds. Thus, the intended use does not lend patentability to the instantly claimed compounds. In addition, there is no requirement that the prior art must suggest that the compound(s) will have the same or similar utility as that discovered by applicant in order to support a legal conclusion of obviousness. In re Dillon, 919 F.2d 688, 696, 16 USPQ 2d 1897, 1904 (Fed. Cir. 1990). An obviousness rejection is proper as long as the prior art suggests a reason or provides a motivation to make the claimed invention. The references teach the compounds are useful in the treatment of various disorders including psoriasis, prostatic cancer, myocardial failure and enhancing the healing of wounds. The ordinary artisan would be motivated to make any of the species taught by the prior art, including those of the instant claims, because he would have the reasonable expectation that any of the species of the genus taught by the prior art would have similar properties and, thus, the same use as the genus as a whole.

Applicant also argues that the prior art does not provide any data for 1 $\alpha$ -hydroxyvitamin D<sub>5</sub>. It should be noted that the rejections are one of obviousness and

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not anticipation. It should also be noted, that the references are not limited to the working examples, but, are evaluated based on what they teach one of ordinary skill in the art. Thus, the fact that the instantly claimed compound is not exemplified and/or discussed in the prior art does not eliminate the fact that based on the disclosure of the prior art, the claimed compounds would have been obvious to the ordinary artisan.

For these reasons and those given in Paper No. 5, the rejections of (1) claims 1-6 and 10-14 under 35 USC 103(a) over (1) Holick et al. ('538); (2) Holick et al. ('643); (3) Bishop et al. ('429) and claims 1-4 and 10-12 under 35 USC 103(a) over Gulbrandsen et al. ('790) are maintained and claims 15-19 are rejected under 35 USC 103(a) over (1) Holick et al. ('538); (2) Holick et al. ('643); (3) Bishop et al. ('429) and claims 15-17 are rejected under 35 USC 103(a) over Gulbrandsen et al. ('790).

#### **Other Matters**

8. Applicant's declaration filed July 8, 1999 were considered but not persuasive for the following reason.

The declarations do not include a true side-by-side comparison of the closest prior art compound and the claimed invention. Applicant makes comparison between data shown in the prior art and that recited by the present specification for a showing of unexpected results. However, the ordinary artisan would know that in the research art, a number of factors can contribute to the results obtained such as environmental

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factors and the researcher doing said experiment(s). It is very common in the research art for the results obtained by one researcher to be very different from those obtained by another researcher even if both researchers are in the same laboratory under identical environmental conditions. The difference can be even greater when one compares results obtained from one laboratory to those from another laboratory. Therefore, applicant's showing of unexpected results is not a true side-by-side comparison of the closest prior art compound with the claimed compounds and, thus is not persuasive.

It is also noted that a declaration based on factual evidence carries greater weight than that based on opinion(s). Therefore, Dr. Nelson's declaration was considered but because of the lack of factual evidence(s) was not persuasive. On the other hand, Dr. Mehta's declaration was not persuasive because it does not include a comparison between the closest the prior art compound and the claimed compounds.

It should be noted that the prior art indicated that the compounds have a lower tendency or inability to cause hypercalcemia and/or hypercalciuria (see Bishop, col. 5, lines 60-67). One of ordinary skill in the art would expect compounds having similar structure to those taught by Bishop to have similar properties and, thus, a lower tendency or inability to cause hypercalcemia and/or hypercalciuria as taught by the prior art.



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### ***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

### ***Telephone Inquiry Contacts***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara Badio whose telephone number is (703) 308-4595. The examiner can normally be reached between 7:30 am and 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

BB

September 2, 1999

  
JOSE C. DEES  
SUPERVISORY PATENT EXAMINER

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